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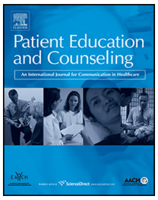

Do participation and personalization matter? A model-driven evaluation of an Internet-based patient education intervention for fibromyalgia patients

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ABSTRACT

Objectives: To evaluate the effectiveness of an Internet-based patient education intervention, which was designed upon principles of personalization and participatory design.
Methods: Fifteen months after the first release of the website, 209 fibromyalgia patients recruited through health professionals completed an online questionnaire to assess patients' use of the website, health knowledge, self-management behavior, and health outcomes. These constructs were combined into an a-priory model that was tested using a structural equation modeling approach.
Results: Results show that the usage of certain tools of the website – designed and personalized involving the end users – impacts patients' health knowledge, which in turn impacts self-management. Improvements in self-management ultimately lower the impact of Fibromyalgia Syndrome leading to better health outcomes.
Conclusion: This study empirically confirmed that the adoption of a participatory approach to the design of eHealth interventions and the use of personalized contents enhance the overall effectiveness of systems.
Practice implications: More time and effort should be invested in involving patients in the preliminary phases of the development of Internet-based patient education interventions and in the definition of models that can guide the systems' evaluation beyond technology-related variables such as usability, accessibility or adoption.

1. Introduction

This paper introduces and evaluates a model of the effects of an Internet-based patient education system designed with principles borrowed from Health Communication, Artificial Intelligence (AI) and User Modeling (UM) research. Specifically, the system adopted a bottom-up approach to the design of the main functionalities, in line with concepts such as personalization/adaptivity [1,2] and participatory design [3,4]. The involvement of the end users in the design process of eHealth interventions and the elaboration of tailored messages are two factors deemed to enhance the overall interventions' effectiveness [5–7]. In line with this claim, the study combines Health Communication, Artificial Intelligence, and User Modeling in two ways: first, it evaluates a system largely based on personalization and participation principles and, second, it does so by advancing an a priori model of their impact on patients' knowledge, self-management, and health outcomes. This model, once tested and refined, can help AI researchers to improve the evaluation of their own systems, going beyond system-related constructs such as usability and adoption towards the measurement of the actual impact of a system on patients' cognitive, psychological, and physiological outcomes. Indeed, such a need for evaluating AI systems beyond their intrinsic characteristics has received attention in the last decade of AI literature. For example, Mellish and Dale [8] and Reiter et al. [9] recognized that a "task evaluation" grounded on underlying theories can prove helpful to gain a better understanding of the real impact of AI interventions. Along the same line Smith et al. [10] stress the need to provide health professionals with evidence of the effectiveness of AI systems, especially concerning health outcomes. However, in the health communication literature it is well known that the direct assessment of health outcomes can prove difficult without an understanding of the possible pathways of change between adoption and outcomes [11]. For this reason, this study advances a model of indirect or mediated effects between the usage of an eHealth system and health outcomes, involving the concepts of health knowledge [12] and self-management [13] as useful constructs to include in a model-driven system evaluation.

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In order to shed light on the rationale behind the present investigation, we first propose a brief review of Internet-based patient education. We then introduce the specific intervention under analysis and illustrate how personalization and participations principles contributed to its design, eventually illustrating the model that was tested with a group of chronically ill patients, focusing mainly on the sections devoted to knowledge improvement. General conclusions about the model's predictive power and its role in systems' evaluations are eventually discussed.

1.1. Internet-based patient education

People suffering from chronic diseases constantly live in a peculiar situation. They are faced with the problem of keeping a balance between the need to adhere to a treatment and the need to live their everyday life and activities as normally as possible. In other words, they must learn how to self-manage their condition [13]. Diseases like cancer, diabetes, depression, low back pain, arthritis, fibromyalgia, though with different symptoms and consequences, all require a constant action by the patient. This need of being informed, monitored, and supported by the health professionals often leads patients to turn to the Internet to seek help [14].

A growing body of literature shows that the Internet can have a positive impact on patients affected by chronic diseases [15,16]. Different kinds of interventions proved to be effective to some extent, such as online-support groups [17], tailored messages [18], online exercises [19] and a combination of these strategies in a unified online self-management program [20,21]. A systematic review of studies focused on Internet-based intervention across a variety of chronic conditions (mental health, diabetes, cardiovascular disorders, cancer, pulmonary disorders, back pain, and others) showed that technology-based delivery of self-management programs is a viable alternative to traditional methods of delivery [22]. The majority of the 27 randomized studies included in the review reported that Internet-based interventions were significantly more effective than routine medical care in improving self-management skills and health outcomes.

1.2. The Internet-based intervention ONESELF

This study focuses on the evaluation of a specific Internet-based intervention, called ONESELF (www.oneself.ch), designed as an interactive tool to enhance self-management and health outcomes of patients affected by Fibromyalgia Syndrome (FMS). FMS is a condition characterized by chronic widespread pain and tenderness in 11 or more of the 18 specific tender point sites [23]. Although the medical evidence is still lacking precise diagnostic criteria for FMS, there are three major symptoms that are usually associated with the disease: pain, sleep disorders and fatigue [24–26]. Alongside these somatic factors, there are other psychological dimensions that are observed in fibromyalgia patients, such as anxiety, stress, depression and many more [27–29].

ONESELF was developed in collaboration with health professionals (rheumatologists, physiotherapists, general practitioners) for consistency with Evidence Based Medicine guidelines. Patients were involved since the very first phases of development in an iterative participatory process: they used a specific function (an *online forum*) to discuss relevant issues and functionalities they found to be personally relevant. These discussions generated two major outcomes: first, some topics raised were translated into articles and included in a *virtual library* and, second, some sections targeted to the users' needs were created (a *virtual gymnasium*, a *first aid* section, a *frequently asked questions* section, *testimonies*, and a *chat room*). To illustrate the process, consider the following excerpt from the online forum (translation from Italian made by the authors): "*Thanks for the touching testimony. It would be great to have such stories collected – for me and for the others – to share what works and what doesn't*. . ." (User G in response to a discussion on FMS at the workplace). The need for a place to access share life experiences emerged from this post and others in the discussion. The need was identified, discussed within the team, and translated into a new functionality: the *testimonies* section.

The application enabled asynchronous and synchronous interactions with health professionals and laypeople. Asynchronous interaction with health professionals was reached through the *virtual library* that provided users with relevant information on the disease. The *first aid* and the *frequently asked questions* section (*FAQ*) published brief and practical information on the syndrome management. The *virtual gymnasium* provided patients with tailored multimedia contents on several physical exercises that constitute the wider part of the non-pharmacological treatment of FMS. Eventually, the section on *testimonies*, where patients could post their stories and comment on stories of other people suffering from the same health condition, enhanced the dimension of social support. Synchronous interaction was designed and implemented via the *online forum* and the *chat room*. Patients used these tools to communicate with the physicians and among themselves. Since its first release in June 2008, more than 600 fibromyalgia patients mostly from Switzerland and Italy have used ONESELF.

1.3. The model of ONESELF effects

The purpose of ONESELF was to improve patients' self-management and health outcomes by increasing their knowledge through information, and empowerment through the provision of social support. Given that the different functionalities were defined and designed following users' indications, one would expect a significant impact of each section on these constructs. More specifically, patients' knowledge of FMS is assumed to be impacted by the use of the virtual library, which provided information on the syndrome, the virtual gymnasium, which taught users how to perform physical exercises to relieve pain, and the FAQ section, which provided users with practical information on the management of the syndrome. Patients' empowerment is assumed to be impacted by the online forum, which allowed users to exchange their experience of pain with health professionals and other laypeople, the chat, which allowed the same kind of support in a synchronous fashion, and the section on testimonies, which provided patients with video and textual material on coping experiences of other sufferers. In the present study, we focus on the evaluation of the informative sections devoted to knowledge improvement (virtual library, FAQ, virtual gymnasium).

The relationship between increased knowledge and behavior (in the present case, self-management) has been investigated in the literature on health education interventions, defined as "consciously constructed opportunities for learning involving some form of communication designed to improve health literacy, including improving knowledge, and developing life skills which are conducive to individual and community health" [30]. The literature conveys different conceptualizations of health literacy. A shared definition has been provided by Ratzan and Parker [31] who defined health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decision". Improving health literacy is necessary since people with limited health literacy report poorer overall health, they are less likely to make use of preventive screenings, they have a poorer understanding of treatment and a lower adherence to medical regimes, they make use of medical services in later stages of their diseases, and therefore are more likely to be hospitalized causing an enormous financial burden for the healthcare system [32].

A number of frameworks have been developed to show the relationship between health literacy, health behavior, and health outcomes [12,32–34]. They claim that health literacy is related to health knowledge, which in turn determines health behavior and health outcomes.

Moving from these considerations, we designed a model that aims to explain the pathways from the usage of ONESELF's informative sections and patients' knowledge, self-management, and health outcomes. As expanded in the methodological section, self-management is operationalized in terms of physical exercise and drug intake. The postulated model is represented in Fig. 1.

According to the model in Fig. 1, the usage of the virtual library, the FAQ section, and the virtual gymnasium impacts patients' knowledge, which, in turn, impacts their level of physical exercise. Hence, the level of exercise impacts the amount of health outcomes. This relationship is partially mediated by the level of drug intake. These relationships can be translated in a set of directional hypotheses:

H1. The more a patient affected by FMS uses the informative sections of ONESELF, the more knowledgeable s/he becomes about the disease and self-management strategies.

H1a. The more a patient uses the virtual library, the more knowledgeable s/he becomes.

H1b. The more a patient uses the FAQ section, the more knowledgeable s/he becomes.

H1c. The more a patient uses the virtual gymnasium, the more knowledgeable s/he becomes.

H2. The more knowledgeable a patient is, the more s/he engages in physical exercise to self-manage his/her condition.

H3. The more a patient is engaged in physical exercise to self-manage his/her condition, the less drugs (such as painkillers) s/he consumes.

H4. The less a patient consumes drugs, the less s/he experiences negative health outcomes.

H5. The more a patient is engaged in physical exercise to self-manage his/her condition, the less s/he experiences negative health outcomes.

2. Methods

2.1. Participants

The participants of the study were 209 patients who have suffered from FMS on average for 5.6 years (SD = ±4.7). Since mainly women are affected by FMS [35], the sample consisted of 95 percent female and 5 percent male patients between the age 25 and 74. The mean age was 49 years (SD = ±10.0). The majority of patients (95 percent) completed at least 8 years of school, of which 82 percent also reported to have a high school or a university degree. ONESELF was designed for Italian-speaking users. Thus, 56 percent of the participants had Italian nationality, 42 percent Swiss nationality, and 2 percent were of other nationalities, however, fluent in Italian.

2.2. Data collection

This is a cross-sectional study where patients were recruited by their physicians. Inclusion criteria were: (a) availability of Internet access, (b) sufficient confidence in using a computer (self-reported), and (c) formal diagnosis received from a rheumatologist. Patients who agreed to participate in the study were asked to subscribe to ONESELF. Although ONESELF was first released in June 2008, half of the users suffering from FMS subscribed to website only after December 10, 2008. In September 2009, emails were sent to the patients with a link to an online questionnaire to be completed by the patients themselves. All patients were asked to agree to an Informed Consent statement before starting the online questionnaire. The average number of days between the date when patients subscribed to the website and the date when data were collected was 167 days (SD = ±67.6).

2.3. Measures

Data were collected by the means of an online questionnaire. Measures relevant to test the assumed model assessed the usage of website applications, knowledge about FMS and its management, self-management indicators, and health outcomes.

Usage of website applications was measured as the frequency with which patients visited each application to retrieve information or get social support. It was assessed on an ordinal scale where patients indicated if they never used an application or if they used it 1–2 times, 3–5 times, 6–10 times, 11–20 times, or more than 20 times. In order to test the impact of informative applications (virtual library, virtual gymnasium, FAQ) on knowledge about FMS and its management, the median split method was used to create three dummy variables where 0 indicates "low frequency" and 1 indicates "high frequency" according to the median for each application (median for virtual library = "1–2 times", median for virtual gymnasium = "1–2 times", median for FAQ = "3–5 times"). This method of dichotomization is criticized for various reasons, including loss in individual differences and reduction of effect size [36]. However, it produced two equally sized groups for each informative application necessary for the further analysis where a structural equation modeling approach was used. Conceptually, these groups still reflect the frequency of usage, and can thus convey meaningful results related to the effectiveness of the application.

Knowledge about FMS and its management was assessed with ten multiple-choice questions adapted from the website of the Mayo Clinic (www.mayoclinic.com [Last visit May 2008]). Questions covered symptoms and prevalence of FMS, treatment options, the effectiveness of medication, and self-management strategies. The proposed answers included only one correct

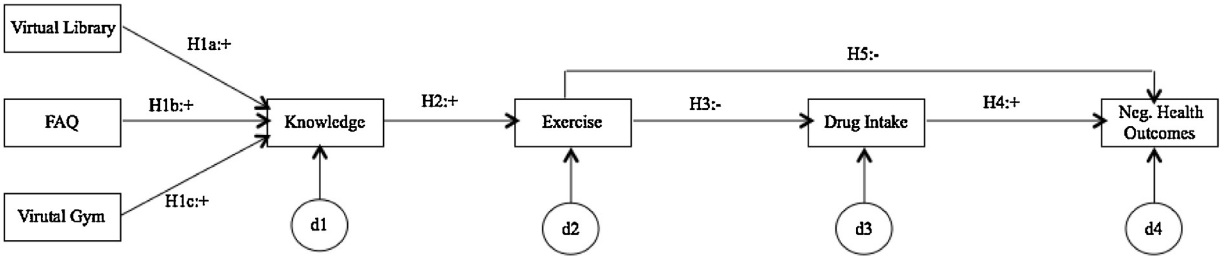

Fig. 1. The model of ONESELF effects. Exogenous variables are allowed to be correlated.

alternative. To avoid guessing, an "I don't know" option was added to each set of proposed answers. All correct answers were summed to get a single knowledge score ranging from 0 to 10. In the present sample the average number of correct answers was 6.7 (SD = ±1.7).

Self-management was assessed by two single indicators based on patients' self-report. One indicator assessed whether patients have changed the amount of physical activity since subscribed to ONESELF (*Exercise*) on a 5-point scale. The other indicator assessed whether they have reduced the drug intake for their FMS since subscribed to the website (*Drug Intake*) on a 4-point scale.

(Negative) health outcomes were measured with the Fibromyalgia Impact Questionnaire (*FIQ*) [37–39]. The *FIQ* is a validated questionnaire that consists of 20 indicators to assess patients' disability to carry out everyday activities, patients' intensity of pain, and the interference of FMS on patients' sleep and emotional state. The *FIQ* is a self-report measure that provides a single score ranging from 0 to 100 where a higher score indicates a greater impact of FMS on the patient (*Negative Health Outcomes*). According to Bennett [38] the average FMS patients scores about 50. In the present sample the average score was 54 (SD = ±20.1).

3. Results

3.1. Website usage and general evaluation

Based on patients' self-report, the applications of ONESELF that provide social support (online forum, section on testimonies, chat) were used more often than applications with information about FMS (virtual library, virtual gymnasium, FAQ). Half of the 209 patients visited the online forum and the section on testimonies at least 3–5 times, whereas the virtual library and the virtual gymnasium were used by half of the sample only 1–2 times. Two exceptions are the chat and the FAQ section. In contrast to the other two social support applications, the chat was not used at all by 57 percent and only 1–2 times by 22 percent of the patients. And whereas the virtual library and the virtual gymnasium as two informative applications were used less frequently, the FAQ section was visited by 48 percent at least 3–5 times. Accordingly, the chat was considered the least, and the FAQ section the most useful application rated on a 7-point Likert scale (mean for chat = 3.1, SD = ±2.3; mean for FAQ = 5.0, SD = ±2.0, where 1 = "not useful at all" and 7 = "completely useful"). All in all ONESELF received a positive feedback with 88 percent being quite or completely satisfied with the website.

3.2. Model results

Data were analyzed using a structural equation modeling approach. The model in Fig. 1 was evaluated with AMOS 18.0 using a maximum likelihood algorithm. Prior to analysis, the data were evaluated for multivariate outliers by examining leverage indices for each individual. Outliers were defined as a leverage score four times higher than the mean leverage, which was 0.08. Two outliers were detected. They represent the only two individuals who scored 0 in the knowledge test. Model-based outliers were evaluated using a limited information approach in which each predictor was separately regressed onto the variable on which it has a direct effect. The analysis used ordinary least squares regression. Standardized dfbetas were examined for each individual and each predictor. An influential model-based outlier was defined as any individual with an absolute standardized dfbeta greater than 1 for a given coefficient. No model-based outliers were evident, and thus the decision has been made to keep the two non-model-based outliers.

Multivariate normality was evaluated using Mardia's test. The multivariate coefficient was not statistically significant. Univariate indices of skewness and kurtosis were examined to evaluate the normal distribution for each variable in the model. The largest absolute value for skewness was 0.83 and for kurtosis 1.34. Given that normality was not considered to be an issue.

A full information maximum likelihood method was used to deal with missing values. To evaluate the model, goodness of fit indices were examined. The overall chi-square test of model fit was statistically significant (χ^2 (11) = 37.41, $p < 0.000$). The Root Mean Square Error of Approximation (RSMEA) was 0.11, and the p value for the test of close fit was 0.01. The Comparative Fit Index (CFI) was 0.77. All indices point toward poor model fit. The standardized residual covariances revealed some statistically significant points of ill-fit in the model. Furthermore, the modification indices suggested adding in the model a direct path from *Virtual Gym* to *Exercise*, which would lead to a drop in the chi-square by 25.79 units. The suggested path is theoretically sound, meaning that individuals who use the virtual gymnasium more frequently also engage in physical activity more often inspired by the exercises proposed and taught to them. After adding the direct path from *Virtual Gym* to *Exercise*, the goodness of fit indices changed considerably. For the modified model, the chi-square test of model fit was statistically non-significant ($\chi^2(12) = 13.58$, $p < 0.328$). The RSMEA was 0.00, and the p value for the test of close fit was 0.73. The Comparative Fit Index (CFI) was 0.99. All indices now point toward good model fit. The standardized residual covariances revealed only one statistically significant point of ill-fit in the model, but the modification indices showed no more theoretically sound suggestions to improve the chi-square.

Fig. 2 shows the final model with all significant path coefficients. For purposes of presentation, the correlations between exogenous variables are omitted. The residuals indicate the proportion of unexplained variance in the endogenous variables. The application usage variables in the model were able to account for approximately 3 percent of the variance in *Knowledge*. *Knowledge* and the usage of *Virtual Gym* explain 14 percent of the variance in *Exercise*. *Exercise* accounted for 10 percent of the variance in *Drug Intake*, which in turn explained 10 percent of the variance in *Negative Health Outcomes*.

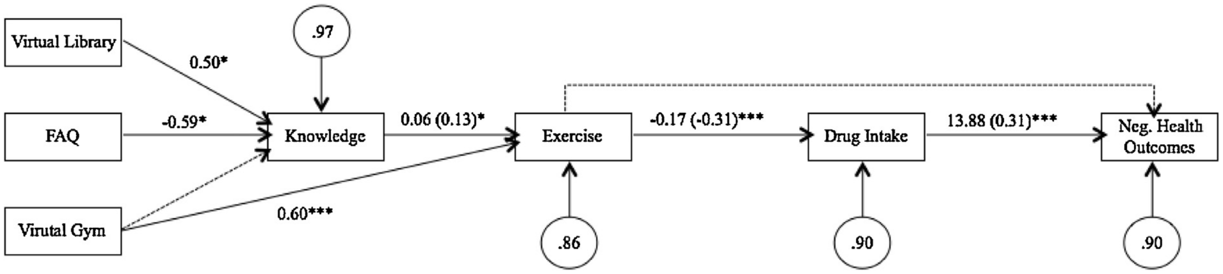

Fig. 2. Final model with unstandardized coefficients; standardized coefficients in parentheses; *$p < 0.05$, ***$p < 0.001$, dashed arrow indicates no significant path coefficient. Exogenous variables are allowed to be correlated.

The path coefficients from *Virtual Library*, *FAQ*, and *Virtual Gym* to *Knowledge* (and *Exercise* respectively) represents mean differences between the patients that used the applications more frequently and the ones who used them less frequently, according to the median split of each informative application. Knowledge of patients using the virtual library at least 3–5 times (high frequency group) was significantly higher than the knowledge of patients using the virtual library up to 2 times (low frequency group). The knowledge of patients using the FAQ section at least 6–10 times (high frequency group) was significantly lower than the knowledge of patients using the FAQ section up to 5 times (low frequency group). This result can be explained by the fact that the FAQ section was consulted only by patients whose level of prior knowledge was low. Unfortunately, due to the cross-sectional nature of the dataset, it is not possible to control for autoregressive effects of knowledge. This kind of control can invert the direction of the path coefficient. The usage of the virtual gymnasium did not have a significant impact on patients' knowledge. However, patients using the virtual gymnasium at least 3–5 times (high frequency group) reported a significantly higher amount of physical exercise than the patients using the virtual gymnasium up to 2 times (low frequency group). Moreover, knowledge had a significant impact on physical exercise, meaning that a one score increase in knowledge was predicted to increase the amount of physical exercise by 0.06 units. The amount of physical exercise had a significant impact on drug intake, meaning that a one-unit increase in physical exercise was predicted to decrease the amount of drug intake by 0.17 units. Eventually, the level of drug intake significantly affected negative health outcomes. This means that a one-unit decrease in drug intake predicted a decrease of 13.88 units on the *FIQ* score (which corresponds to an improvement in health status).

In sum, hypotheses H1a, H2, H3, and H4 were confirmed. For what concerns H1b, the reversed relationship can be due to a lack of control for prior knowledge, as previously explained. Regarding H1c, contrary to our assumption, analyses showed a theoretically sound direct relationship between the usage of the virtual gymnasium and the level of physical exercise, without the mediation of knowledge. In the same line, H5 could not be confirmed, as the relationship between the level of physical exercise and improvement in health outcomes turned out to be fully mediated by the level of drug intake.

4. Discussion and conclusion

4.1. Discussion

The model-driven evaluation of the Internet-based intervention was overall satisfactory. The usage of informative applications could explain 3 percent of the variance in patients' knowledge about FMS. Although this result may seem weak, it should be interpreted in light of the many other factors that can intervene in the process of knowledge acquisition such as patient-oriented information provided by health professionals and other healthcare providers as well as traditional media and other online applications. In particular, the effect of the usage of virtual gymnasium on the amount of physical exercise was considerable. Together with increased knowledge, it could explain 14 percent of the variance of the amount of exercise. This improvement of the physical component of self-management resulted in a significant reduction of drug intake. This reduction accounted for 10 percent of the variance in negative health outcomes, meaning that the improvement in self-management behavior positively impacted patients' health status. Despite these significant effects, the relationships assumed in the model of Internet effects and confirmed by the structural analysis should not be interpreted in a strictly causal sense. Since the data come from a cross-sectional survey, no causality can be demonstrated. However, previous reviews on quantitative/experimental studies confirmed the relationships between Internet-based applications and health knowledge [40], and knowledge, self-management and health outcomes [41,42]. Conclusions from these studies support the soundness of the theoretical model on which the evaluation was based.

Some limitations of the study should be mentioned. First, measures are mainly self-report, which may lead to an under- or over-estimation of the usage of applications and self-management behavior as well as health outcomes. Second, the model was tested with single manifest indicators, which do not reflect the multidimensionality of some constructs. Third, exogenous variables took into account only the frequency with which the applications were used. However, knowledge acquisition also depends on the quality of interaction. For example, a patient who visited the virtual library only once but spent many hours to study the published material can be comparable to a patient who visits the virtual library more than once but spent less time reading its contents. Fourth, the cross-sectional nature of the interventions does not allow to conclude that the observed relations in the model are causal in nature. A last limitation was the lack of consideration of the interactive features (i.e., the sections more related to empowerment such as the online forum or the chat room) that may improve the predictive power of the model.

4.2. Conclusion

The evaluation of Internet-based interventions for chronically ill patients is essential to gain insights into the mechanisms that lead from their applications to improved health outcomes. While several studies on this topic are strictly experimental, theory-driven evaluations are mostly needed. In this respect, our study contributes to the discussion of the effectiveness of Internet-based interventions to improve self-management of chronically ill patients while keeping a theoretical perspective on the issue. Furthermore, by changing the focal independent variables in the model (i.e., variables related to the usage of the intervention), the model can be easily used to test other AI systems meant to impact patients' outcomes. This way, AI research can gain insights from Health Communication and health behavior models to extend the scope of systems' evaluation beyond system-related variables such as usability, accessibility, and adoption.

4.3. Practice implications

This study empirically confirmed that the adoption of a participatory approach to the design of eHealth interventions and the use of personalized contents enhance the overall effectiveness of systems. Therefore, more time and effort should be invested in involving patients in the preliminary phases of systems' development, maximizing the likelihood to observe the desired effects. In addition, the design should be theory-driven, so that every component/functionality that stems out of patients' requirements is clearly targeted to enhance specific outcomes (e.g., patients' knowledge of FMS). This kind of matching guarantees the possibility to conduct robust evaluations of systems and to increase the generalizability of results, eventually leading to the definition of best practices in eHealth communication interventions' implementation.

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Conflict of interest

There is no conflict of interest of the authors.

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